

Routine commissioning of HIV preexposure prophylaxis (PrEP) in England

Monitoring and evaluation framework

Version 1

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Summary

The UK Health Security Agency (UKHSA) has developed a monitoring and evaluation framework to support local authorities, specialist sexual health services (SHSs), and other key stakeholders with the delivery of HIV pre-exposure prophylaxis (PrEP). The framework consists of a series of indicators to inform service improvement in PrEP commissioning and delivery, as well as the elimination of HIV transmission and broader sexually transmitted infection (STI) control. The indicators will be published within existing HIV and STI surveillance outputs starting in 2022, once a full year of data has been reported to UKHSA.

Provisional data for January to June 2021 suggests that at this time, there is likely to be under reporting and inconsistent use of PrEP surveillance codes reported through the GUMCAD STI Surveillance System. These data quality issues should be considered when interpreting current data on PrEP service provision, available to service providers and commissioners through the HIV and STI Data Exchange.

Monitoring and evaluation of PrEP delivery is essential to understand the effectiveness of PrEP and its place within wider HIV combination prevention strategies. However, this is dependent on the completeness and quality of data. UKHSA is actively working with local providers to support PrEP reporting and the quality of coding.

Introduction

HIV pre-exposure prophylaxis (PrEP) involves the use of antiretroviral medicines in individuals who are HIV negative to reduce the risk of acquiring HIV (1, 2, 3). In March 2020, the Secretary of State for Health and Social Care announced that funding would be distributed to local authorities to allow the routine commissioning of HIV PrEP. As part of a combination approach to HIV prevention, the roll out of routine PrEP commissioning began in England in the autumn of 2020. Specialist sexual health services¹ (SHSs) are responsible for the delivery of PrEP to those at higher risk of acquiring HIV. NHS England and Improvement continue to fund the drug costs for PrEP, as they did for the PrEP Impact Trial².

This report provides an overview of a national framework to monitor and evaluate the delivery of PrEP in England. The framework includes a set of indicators to be published within existing HIV and STI surveillance outputs.

¹ Specialist (level 3) sexual health services refers to genitourinary medicine (GUM) and integrated GUM or sexual and reproductive health (SRH) services. Further details on the levels of sexual healthcare provision are provided in the <u>BASHH Standards for the Management of STIs (Appendix B)</u>.

² The PrEP Impact Trial was a non-interventional, non-randomised, pragmatic health technology assessment of PrEP implementation. The trial was established to answer real-world questions about PrEP eligibility, uptake and duration of use, as well as the impact of PrEP scale-up on HIV and other STIs. Final visits for the Impact Trial were completed by the end of November 2020 and the results are expected to be published later this year.

Monitoring and evaluation framework for PrEP

UKHSA has developed a monitoring and evaluation framework to support local authorities, SHSs and other key stakeholders with the delivery of PrEP. The framework is based on the World Health Organization (WHO)'s <u>implementation tool for pre-exposure prophylaxis of HIV infection</u> ($\underline{4}$, $\underline{5}$), and was developed with input from internal and external stakeholders within UKHSA, the NHS, local government, academia, and HIV and sexual health community-based and charitable organisations.

Aim and objectives

Aligned with the ambition to <u>end new HIV transmissions in England by 2030</u>, the aim of the monitoring and evaluation framework is to define a series of indicators to support the delivery of PrEP at a national, regional and local level. Specific objectives of the framework are to:

- inform continuous service improvement in PrEP commissioning and delivery using existing data sources
- help identify and initiate ways to reduce potential health inequalities

Framework indicators

There are 7 indicators within the PrEP monitoring and evaluation framework for England. The indicators are grouped under 2 themes:

1. Service delivery evaluation

This focusses on components related to the delivery of PrEP to key populations, including need, uptake, and use. It is intended that these indicators will be used to inform service delivery and improvement and help reduce health inequalities. There are 5 indicators within this element of the framework – indicators 1.1 to 1.3 in Figure 1 and Table 1.

2. Epidemiology of HIV and STIs among PrEP users

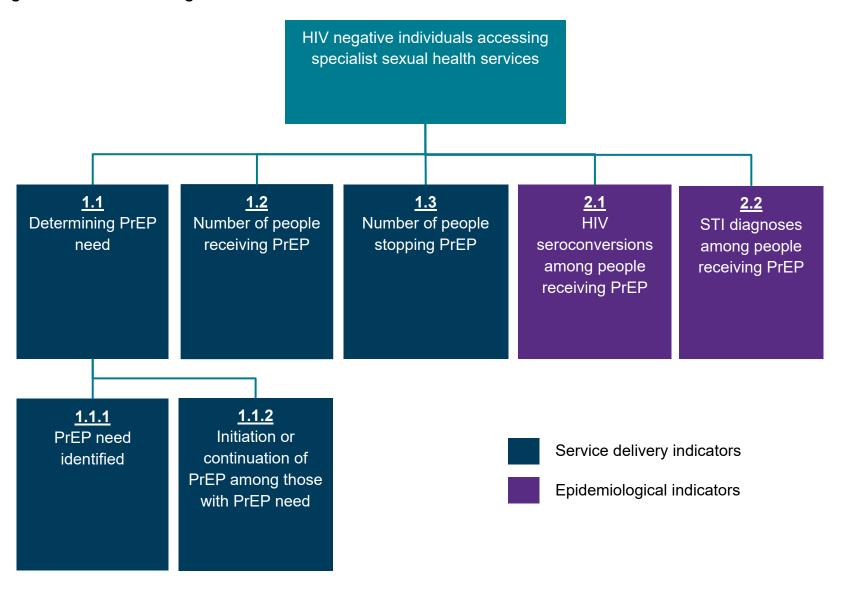
This focuses on HIV and STI outcomes among PrEP users. It is intended that these indicators will be used to inform the elimination of HIV transmission and broader STI control. There are 2 indicators within this element of the framework – indicators 2.1 and 2.2 in Figure 1 and Table 1.

A summary of these indicators is shown in the flow diagram in <u>Figure 1</u> and a description of the indicator definition, numerator and denominator is provided in <u>Table 1</u>. Detailed information on the rationale and definition for each indicator, including the numerator, denominator, value type, and calculation methodology are provided in the <u>Appendix</u>.

Routine commissioning of HIV PrEP in England: monitoring and evaluation framework

It is recommended that the indicators are not used separately, but should be considered together as this will provide an integrated understanding of PrEP delivery and impact at national, regional and local levels.

Figure 1. PrEP monitoring and evaluation framework overview



The PrEP indicators will be published annually within existing HIV and STI surveillance outputs, including the <u>Sexual and reproductive health (SRH) profiles</u>. The indicators will contain data from January 2021 onwards.

A phased approach to publication will take place starting in 2022, after a full year of data for 2021 has been reported to the UKHSA through the GUMCAD STI Surveillance System. This approach is in line with the standard method for publishing new HIV and STI data outputs.

Where possible, and depending on the intended surveillance output, the indicators will be presented by:

- age group
- gender
- key population such as gay, bisexual and other men who have sex with men (MSM), heterosexuals, Black African heterosexuals, trans and gender diverse people
- ethnic group
- geographical area³

Small numbers will be suppressed in line with standard data sharing and confidentiality guidelines. Please refer to the HIV and STI data sharing policy for further details.

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³ Geographical area refers to lower tier local authority, upper tier local authority, UKHSA centre, UKHSA region or national level, depending on the output. Service and residence data will be available: Service data represent activity at specialist SHSs located in England, that is where people access care and not where they reside. Residence data represent activity by area of patient residence and exclude people accessing specialist SHSs located in England who are residents in Wales, Scotland, Northern Ireland or abroad.

The table below provides an overview of the definition, numerator and denominator for each indicator in the monitoring and evaluation framework for England. Click on the hyperlink in the indicator field to view detailed information in the <u>Appendix</u>. Please refer to <u>Figure 1</u> for a summary of the indicators in the form of a flow diagram.

Table 1. PrEP monitoring and evaluation framework indicators

Indicator	Definition	Numerator	Denominator
1.1: Determining PrEP need	Proportion of all HIV negative individuals accessing specialist SHSs with PrEP need.	The number of HIV negative individuals accessing specialist SHSs with PrEP need.	The number of HIV negative individuals accessing specialist SHSs.
1.1.1: PrEP need identified	Proportion of all HIV negative individuals with estimated PrEP need (indicator 1.1) who had this need identified.	The number of HIV negative individuals accessing specialist SHSs with PrEP need identified.	The number of HIV negative individuals accessing specialist SHSs with PrEP need (numerator of indicator 1.1).
1.1.2: Initiation or continuation of PrEP among those with PrEP need	Proportion of all HIV negative individuals with estimated PrEP need (indicator 1.1) who started or continued PrEP.	The number of HIV negative individuals accessing specialist SHSs who started or continued PrEP.	The number of HIV negative individuals accessing specialist SHSs with PrEP need (numerator of indicator 1.1).
1.2: Number of people receiving PrEP	Absolute number of individuals accessing specialist SHSs who are receiving PrEP for each quarter.	The number of HIV negative individuals accessing specialist SHSs who are receiving PrEP in each quarter.	Not applicable
1.3: Number of people stopping PrEP	Absolute number of individuals accessing specialist SHSs stopping PrEP in each quarter.	The number of PrEP users accessing specialist SHSs who stop PrEP in the current quarter.	Not applicable

Indicator	Definition	Numerator	Denominator
2.1: HIV seroconversions among people receiving PrEP	Proportion of people who are newly diagnosed with HIV among individuals accessing specialist SHSs who have received PrEP in the last 12 months.	The number of new HIV diagnoses among individuals accessing specialist SHSs who received PrEP at least once in the last 12 months.	The number of individuals accessing specialist SHSs who received PrEP at least once in the last 12 months.
2.2: STI diagnoses among people receiving PrEP	STI diagnoses among individuals accessing specialist SHSs who received PrEP at least once in the last 12 months.	The number of STI diagnoses among individuals accessing specialist SHSs who received PrEP at least once in the last 12 months.	The number of individuals accessing specialist SHSs who received PrEP at least once in the last 12 months.

Data source

Data for the monitoring and evaluation framework is collected quarterly from specialist SHSs through the national <u>GUMCAD STI Surveillance System</u>. <u>Table 2</u> provides an overview of PrEP data items. Please note that this table is based on the April 2019 version of GUMCAD which includes behavioural, PrEP use and partner notification data (commonly referred to as 'GUMCADv3'). Full details are available in the <u>GUMCAD clinical guidelines</u>.

Table 2. PrEP data items collected via the GUMCAD STI Surveillance System

Data item	Coding options
PrEP eligibility	MSM or transgender woman
	HIV positive partner
	Other high risk
PrEP uptake (that is the	Accepted
outcome of the offer of PrEP)	Declined: patient choice
	Declined: obtained at another source
PrEP regimen	Daily (or near daily)
	Event based (coital)
PrEP prescription	30 tablets
	60 tablets
	90 tablets
	180 tablets
	Other amount
PrEP stop reason	Adverse event
	HIV acquisition
	Patient choice
	No longer eligible
	Other reason
Gender identity	Male (including trans man)
	Female (including trans woman)
Gender at birth	Yes – gender identity is the same as gender assigned at birth
	No – gender identity is not the same as gender assigned at birth

Detailed <u>guidelines on the use of PrEP</u> have been developed by the British HIV Association (BHIVA) and the British Association for Sexual Health and HIV (BASHH). PrEP eligibility categories in the GUMCAD STI Surveillance System are aligned with those in the current version (2018) of the PrEP guidelines.

Data limitations

Data from the GUMCAD STI Surveillance System has limitations which are important to consider when interpreting data related to PrEP delivery and outcomes.

1. Data reporting

GUMCAD includes comprehensive data on people accessing SHSs, therefore the data is not representative of the general population. Estimating PrEP need among people not accessing SHSs is also important but this cannot be captured through national surveillance data sets.

To protect patient confidentiality, individuals are assigned unique clinic-specific patient identification codes, but this means that each individual's GUMCAD records can only be linked within the same specialist SHSs; consultations at 2 or more specialist SHSs by the same individual are not linked. This might overestimate the number of people who are starting PrEP for the first time. However, data from year one of the human papillomavirus virus (HPV) vaccination pilot among MSM attending selected SHSs and HIV clinics found that 87% of those receiving their first vaccine dose attended their usual or local SHS or HIV clinic, and 95% indicated that they would return to the same service for their next vaccine doses (6, 7).

UKHSA makes every effort to ensure the accuracy and completeness of GUMCAD data, including data validation at the point of submission, detailed epidemiological analysis, and the provision of quarterly web-based reports. The latter provide SHSs with the opportunity to regularly review their data. Although SHSs are responsible for the accuracy and completeness of their own GUMCAD data, UKHSA is available to provide support and guidance with regards to coding and reporting.

2. PrEP monitoring and evaluation framework

All data for the PrEP monitoring and evaluation framework relate to people accessing specialist SHSs for STI-related care, including HIV and STI testing. People for whom the attendance was reported as related to reproductive care only are not included.

Under-reporting of PrEP eligibility in GUMCAD might underestimate the number of people accessing specialist SHSs who could benefit from PrEP. To determine PrEP need, the monitoring and evaluation framework will use a pragmatic approach that includes both PrEP eligibility coding and other clinical or demographic characteristics that might indicate higher risk of subsequent HIV acquisition.

It is not possible to exclude those who are considered ineligible for PrEP based on a medical contraindication. This information is not currently captured in GUMCAD.

The indicators in the PrEP monitoring and evaluation framework do not cover all the steps within the WHO Implementation Tool for PrEP, such as achieving adherence.

Data from community-based surveys

Periodic community-based surveys provide an additional mechanism to understand the need for PrEP in the general population and can complement the indicators within the national PrEP monitoring and evaluation framework.

Examples of community-based surveys that could be used to understand population need and access to PrEP include:

- the Gay Men's Sexual Health Survey
- the National Survey of Sexual Attitudes and Lifestyles (<u>Natsal</u>)
- the PrEP User Survey (UKHSA in collaboration with <u>HIV Scotland</u>, <u>iwantPrEPnow</u> and <u>PrEPster</u>) (8, 9)
- the <u>National Institute for Health Research Health Protection Research Unit in Blood</u>
 <u>Borne and Sexually Transmitted Infections</u> Reducing Inequalities and Improving
 Sexual Health survey on STIs, access to services and sexual behaviour during the
 coronavirus (COVID-19) pandemic (RiiSH-COVID) (10)

These community-based surveys could also be used to explore other factors associated with PrEP delivery and use that are not captured through national surveillance data, such as achieving adherence.

Progress towards PrEP monitoring and evaluation

While data for 2021 is not yet complete, UKHSA has undertaken analyses of provisional data on PrEP eligibility, uptake, regimens and prescriptions reported through the GUMCAD STI Surveillance System for January to June 2021 to assess data completeness and quality. These analyses suggest that at this time, there is likely to be under reporting and inconsistent use of PrEP surveillance codes in GUMCAD. Consequently, these data underestimate PrEP activity.

Robust evaluation of PrEP delivery is essential to understand the effectiveness of PrEP and its place within wider HIV combination prevention strategies. However, ongoing monitoring and evaluation is dependent on the completeness and quality of data. SHSs and local authorities have a critical role to play in ensuring that PrEP data collected through GUMCAD and reported to UKHSA is complete and accurate.

UKHSA is actively working with service providers to support PrEP reporting and the quality of coding, including the delivery of PrEP coding webinars and the development of clinic-specific data quality reports. Provisional PrEP data from January 2021 onwards is also available to registered NHS and local authority users through the HIV and STI Data Exchange reports. These restricted-access reports are updated on a quarterly basis and provide information on the number of PrEP codes reported at local, regional and national levels. For further information about the HIV and STI Data Exchange or to request access please email gumcad@phe.gov.uk

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Appendix

Indicator level data specification

1.1: Determining Pr	EP need	Back to overview Table 1
Rationale	This indicator is used to determine PrEP need among people accessing all HIV negative people accessing specialist SHSs who are at substanting receiving PrEP. This assessment of HIV risk is based on a combination rely solely on the presence of specific 'PrEP eligibility' codes as these a not been formally and systematically assessed among all people attend Therefore, in the absence of these specific PrEP eligibility codes other for example, having been prescribed PrEP and other clinical or behavior risk of HIV seroconversion in the year following an attendance. These a below. By using this combination of codes, this indicator includes people receiving PrEP (met need) as well as those with need who are not curre indicator does not relate to better or worse performance as it will vary be populations.	ial HIV risk, and therefore could benefit from of clinical codes in GUMCAD and does not are often missing because PrEP eligibility has ling the service by the health care provider. codes are used to indicate substantial HIV risk, bural variables that are known to indicate higher are listed in the 'Definition of numerator' section e who are having their need for PrEP met by ently receiving PrEP (unmet need). This
Indicator definition	Proportion of all HIV negative individuals accessing specialist SHSs wit	h PrEP need.
Definition of numerator	The number of HIV negative individuals accessing specialist SHSs with PrEP need.	
	PrEP need is defined separately for HIV negative MSM and other population groups. HIV negative MSM who at any time in the last 12 months (including the current attendance) have any of the following reported:	
	PrEP eligibility code	

1.1: Determining PrE	P need	Back to overview Table 1
	PrEP uptake code	
	PrEP regimen code	
	quantity of pills prescribed	
	 received PEPSE (for sexual exposure only) 	
	diagnosis of a rectal bacterial STI	
	diagnosis of syphilis	
	condomless anal sex	
	sexualised drug use	
	HIV negative heterosexual men and heterosexual women who at any tin attendance) have any of the following reported:	ne in the last 12 months (including the current
	PrEP eligibility code	
	PrEP uptake code	
	PrEP regimen codes	
	quantity of pills prescribed	
	received PEPSE (for sexual exposure only)	
	Further work will be done to refine the definition of PrEP need based on	findings from the PrEP Impact Trial.
	Note: Individuals are excluded from the numerator if they attended for S	RH care only.
Definition of	The number of HIV negative individuals accessing specialist SHSs.	
denominator	Note: Individuals are excluded from the denominator if they attended for	SRH care only.
Value type	Proportion	
Methodology	The numerator is divided by the denominator and multiplied by 100.	

1.1.1: PrEP need ide	ntified	Back to overview Table 1
Rationale	This indicator assesses what proportion of individuals accessing specialist SHSs with PrEP need (indicator 1.1) had that need identified at that visit. We use a combination of GUMCAD PrEP activity codes to indicate that PrEP need was identified. These include the presence of a PrEP eligibility code, being prescribed PrEP, or being offered and declining PrEP. This is a key step in being able to start addressing needs. A lower proportion of individuals with eligibility identified indicates that individuals with PrEP need are leaving the service without their need being adequately addressed. Inversely, a higher proportion indicates that individuals are having their need identified even if they left the service without receiving PrEP (for example, they may have declined PrEP or PrEP was medically contraindicated).	
Indicator definition	Proportion of all HIV negative individuals with estimated PrEP need (indic	cator 1.1) who had this need identified.
Definition of numerator	Proportion of all HIV negative individuals with estimated PrEP need (indicator 1.1) who had this need identified. The number of all HIV negative individuals accessing specialist SHSs with PrEP need identified. PrEP need identified includes individuals who at any point in the last 12 months (including the current attendance) have any of the following reported: PrEP eligibility code PrEP uptake code PrEP regimen code quantity of pills prescribed Note: Individuals are excluded from the numerator if they attended for SRH care only.	
Definition of denominator	The number of HIV negative individuals accessing specialist SHSs with F PrEP need is defined separately for HIV negative MSM and other popula	PrEP need (numerator from indicator 1.1).

1.1.1: PrEP need ider	ntified	Back to overview Table 1
HIV negative MSM who at any time in the last 12 months (including the current attendance) have any of the following		
	reported:	
	PrEP eligibility code	
	PrEP uptake code	
	PrEP regimen code	
	quantity of pills prescribed	
	received PEPSE (for sexual exposure only)	
	diagnosis of a rectal bacterial STI	
	diagnosis of syphilis	
	condomless anal sex	
	sexualised drug use	
	HIV negative heterosexual men and heterosexual women who at any time	e in the last 12 months have any of the
	following reported:	·
	PrEP eligibility code	
	PrEP uptake code	
	PrEP regimen codes	
	quantity of pills prescribed	
	received PEPSE (for sexual exposure only)	
	Further work will be done to refine the definition of PrEP need based on f	indings from the <u>PrEP Impact Trial</u> .
	Note: Individuals are excluded from the denominator if they attended for \$	SRH care only.
Value type	Proportion	
Methodology	The numerator is divided by the denominator and multiplied by 100.	

1.1.2: Initiation or co	ontinuation of PrEP among those with PrEP need	Back to overview Table 1
Rationale	This indicator assesses what proportion of individuals accessing specialist SHSs with PrEP need (indicator 1.1) start or continue PrEP. This is a subgroup of those in indicator 1.1.1 which includes people who were offered and declined PrEP or were eligible and were not given PrEP because of medical contraindications. The higher the proportion, the better PrEP need is being met through providing PrEP. A lower proportion indicates that more individuals with need are leaving the service without PrEP, the reason for which will be multifactorial but not possible to describe using GUMCAD.	
Indicator definition	Proportion of all HIV negative individuals with estimated PrEP need (indi	icator 1.1) who started or continued PrEP.
Definition of numerator	The number of all HIV negative individuals accessing specialist SHSs who started or continued PrEP at any time in the last 12 months (including the current attendance) based on reporting of the following:	
	PrEP uptake is accepted or obtained at another source	
	PrEP regimen	
	quantity of pills prescribed	
	Note: Individuals are excluded from the numerator if they attended for SRH care only.	
Definition of denominator	The number of HIV negative individuals accessing specialist SHSs with PrEP need (numerator from indicator 1.1).	
	PrEP need is defined separately for HIV negative MSM and other population groups.	
	HIV negative MSM who at any time in the last 12 months (including the reported:	current attendance) have any of the following
	PrEP eligibility code	
	PrEP uptake code	

1.1.2: Initiation or co	entinuation of PrEP among those with PrEP need	Back to overview Table 1
	PrEP regimen code	
	quantity of pills prescribed	
	received PEPSE (for sexual exposure only)	
	diagnosis of a rectal bacterial STI	
	diagnosis of syphilis	
	condomless anal sex	
	sexualised drug use	
	HIV negative heterosexual men and heterosexual women who at any tim attendance) have any of the following reported:	e in the last 12 months (including the current
	PrEP eligibility code	
	PrEP uptake code	
	PrEP regimen codes	
	quantity of pills prescribed	
	received PEPSE (for sexual exposure only)	
	Further work will be done to refine the definition of PrEP need based on f	findings from the <u>PrEP Impact Trial</u> .
	Note: Individuals are excluded from the numerator if they attended for SF	RH care only.
Value type	Proportion	
Methodology	The numerator is divided by the denominator and multiplied by 100.	

1.2: Number of peop	ole receiving PrEP	Back to overview Table 1
Rationale	This is an estimate of the absolute number of people who are receiving PrEP each quarter either self-sourced or from any specialist SHS. This number includes a mix of new starters, re-starters (people who started following a break in PrEP) and those continuing PrEP through routine commissioning or self-sourced. However, evidence already exists to suggest that the proportion of people self-sourcing has declined in recent years (8). This indicator is intended to be used for service planning purposes. The number alone does not indicate whether PrEP is being delivered to those with greatest need (these are addressed in other indicators). Therefore, an increase or decrease in the estimated number of people provided PrEP should not be used in isolation to indicate an improving or worsening of PrEP provision.	
Indicator definition	Absolute number of individuals who are receiving PrEP for each quarter.	
Definition	 The number of individuals accessing specialist SHSs who are receiving R PrEP uptake accepted or obtained at another source PrEP regimen quantity of pills prescribed The numerator is calculated by counting the number of individuals who here privately in the current reporting quarter (RQ), plus any other attendance at PrEP prescription or who attended for PrEP care (that is obtain specialist SHSs for monitoring). 	ave received a PrEP prescription or sourced dees in the previous quarter (RQ-1) who
Value type	Integer	
Methodology	Aggregation of data	
Notes	GUMCAD does not contain separate codes for starting or continuing PrE whether this can be done by analysing patient attendances within the sai	

1.2: Num	ber of people receiving PrEP	Back to overview Table 1
	attendances between clinics. In addition, analyses of data held locally by the service provider can help to identify the number of people starting, re-starting or continuing PrEP.	
	Defining a 'PrEP user' (the numerator) could be done in didefinition within the five-nations minimum data set (Englar Ireland) (5).	, ,
	PrEP users sourcing PrEP privately may not access speci could assist in understanding how many individuals are so Survey (UKHSA in collaboration with HIV Scotland, iwant	ourcing PrEP privately, for example the annual PrEP User

1.3: Number of people stopping PrEP Back to overview Table 1		Back to overview Table 1
Rationale	This indicator is an assessment of how many PrEP users have stopped taking daily PrEP. The estimate does not solely rely on coding but also takes account of people who have not returned to the same service within 6 months of receiving a prescription for daily PrEP. This is likely to overestimate PrEP discontinuations and interruptions because it assumes individuals who switch between daily and event-based PrEP without returning to the service are no longer taking PrEP. Additionally, within a period of engagement, people may stop but later restart or switch between dosing regimen. This indicator provides a measure of PrEP continuation that could also help to identify issues in service provision or engagement in key population groups.	
Indicator definition	Number of individuals stopping PrEP per quarter	
Definition of numerator	The number of PrEP users accessing specialist SHSs who stop daily PrEP per quarter. The numerator is generated by counting the number of individuals who stopped daily PrEP in the current RQ, plus the number who began or renewed daily PrEP in the previous 2 RQs ((RQ)-2) and have not returned in the current RQ and RQ-1.	

1.3: Number of peo	ople stopping PrEP Back to overview Table 1	
	The number of individuals accessing specialist SHSs who stop daily PrEf	P is based on reporting of the following:
	PrEP uptake accepted or obtained at another source	
	PrEP regimen is daily (or near daily)	
	quantity of pills prescribed	
	PrEP stop reason	
Definition of denominator	Not applicable	
Value type	Integer	
Notes	The PrEP coding options in the GUMCAD STI Surveillance System were reasons for stopping PrEP. Not all clinics currently report PrEP stop reasons basis. Analyses of data held locally by the service provider may help to idengagement in key population groups.	on, but this will be reviewed on an ongoing

2.1: HIV seroconvers	sions among people receiving PrEP	Back to overview Table 1
Rationale	This indicator measures the number of seroconversions among people who have received PrEP in the last 12 months. This is important to monitor PrEP breakthroughs (that is people who take PrEP consistently as prescribed but acquire HIV) and may also help to highlight any issues in PrEP provision, adherence and continuation among key population groups. It focuses on HIV outcomes among PrEP users to help inform HIV elimination. A higher value indicates that PrEP service delivery could be improved. Further investigation into the potential reasons for seroconversion could help to identify any issues.	
Indicator definition	Proportion of people who are newly diagnosed with HIV among individuals accessing specialist SHSs who have received PrEP in the last 12 months	
Definition of numerator	The number of individuals accessing specialist SHSs who had a new HIV diagnosis among individuals who received PrEP (daily or event based) at least once in the last 12 months and who had at least one follow-up HIV test.	

2.1: HIV seroconve	ersions among people receiving PrEP	Back to overview Table 1
Definition of denominator	The number of individuals accessing specialist SHSs who received PrEP (daily or event based) at least once in the last 12 months and who had at least one follow-up HIV test.	
Value type	Proportion	
Methodology	The numerator is divided by the denominator and multiplied by 100.	
Notes	The GUMCAD STI Surveillance System collects data on new HIV diagnoses and these data will be used to estimate seroconversions among people receiving PrEP in combination with a recent negative test. There are additional measures that will be considered within this indicator:	
 the number of current PrEP users (daily and event based) who are newly diagnosed with HIV the number of previous PrEP users (last 6 months, daily and event based) who are newly diagnosed HIV the number of new HIV diagnoses in individuals who are not on PrEP (including those who had PrE 		sed) who are newly diagnosed with

2.2: STI diagnoses ar	nong people receiving PrEP	Back to overview Table 1
Rationale	As part of PrEP monitoring, we will report the number of STIs diagnosed among PrEP users. Further work will be done to define a 'PrEP user', that is the time period prior to an STI diagnosis that someone was prescribed PrEP. It is not proposed that any measure of STIs among PrEP users would be an indicator of success or failure. For many reasons, it is not possible to infer if PrEP use leads to an increase in STIs using the number of STIs diagnosed among PrEP users alone. As part of the PrEP Impact Trial there will be analyses to explore if PrEP users experience more STIs compared to non-PrEP users, taking into account other differences that exist, for example testing frequency.	
Indicator definition	New STI diagnoses (excluding HIV) among individuals accessing special the last 12 months	st SHSs who received PrEP at least once in
Definition of numerator	The number of new STI diagnoses among individuals accessing specialis the last 12 months	t SHSs who received PrEP at least once in

2.2: STI diagnoses a	mong people receiving PrEP	Back to overview Table 1
Definition of denominator	The number of individuals accessing specialist SHSs who received PrEP at least once in the last 12 months	
Value type	Rate (per 1,000 people who received PrEP at least once in the last 12 months)	
Methodology	The numerator is divided by the denominator and multiplied by 1,000.	
Notes	New STI diagnoses include the following: chancroid, chlamydia, donovanosis, gonorrhoea; genital herpes (first episode), <i>Lymphogranuloma venereum</i> (LGV), molluscum contagiosum, <i>Mycoplasma genitalium</i> , non-specific genital infection, pediculosis pubis, pelvic inflammatory disease (PID) and epididymitis, scabies, <i>Shigella flexneri</i> , <i>Shigella sonnei</i> , <i>Shigella</i> spp (unspecified), infectious syphilis: primary, secondary and early latent, trichomoniasis, genital warts (first episode).	

Acknowledgements

Contributors

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Stakeholder engagement

Organisation names as recorded on the stakeholder feedback return:

Africa Advocacy Foundation

Bath and North East Somerset Council

British Association for Sexual Health and HIV (BASHH)

Calderdale and Huddersfield NHS Foundation Trust

Cambridgeshire County Council

Camden and Islington Councils

Central North West London (CNWL) Sexual Health – Surrey

Doncaster and Bassetlaw Hospitals NHS Trust

Epsom and St Helier Hospital

Kent County Council

LGBT Foundation

London Borough of Bexley

London Borough of Redbridge

National AIDS Trust

Norfolk County Council

Nottingham City Council

Portsmouth City Council

Public Health Dorset

Serenity, Sexual Assault Referral Centre, Northampton

Scotland's PrEP Monitoring and Research Group

Surrey Sexual Health and HIV Services

Sutton Local Authority

Routine commissioning of HIV PrEP in England: monitoring and evaluation framework

The Brunswick Centre
The Love Tank CIC
The Men's Room
Torbay Council
Virgin care
Western Sussex Sexual Health Services

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